

REMARKS

In the Office Action dated September 10, 2002, claims 1-16 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable to one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The Examiner stated that the present specification fails to describe any steps or procedures of the claimed expert system. The Examiner stated such missing steps and procedures are essential to the use of the invention as claimed, and therefore one of skill in the art cannot use the invention with the information contained in the present disclosure, and would require undue experimentation.

This rejection is respectfully traversed for the following reasons.

Expert systems, and the expert rules used in such expert systems, are so well known to those of ordinary skill in the art that no further explanation beyond that provided in the present specification is necessary in order to enable a person of ordinary skill in the art to make and use the present invention as claimed. Particularly in the field of medical analysis, the use of such expert systems is well known and well documented, as is the operation thereof. Many such systems are commercially available. As discussed in more detail below, the basic feature on which Applicants rely for patentability of the present claims is the creation of a new expert rule, for use by the expert system in addition to the pre-existing expert rules thereof, from a collection of data obtained from multiple point of care sites. Once a person of ordinary skill in the art is informed by the present disclosure that the new expert rule is to be created from such data, those of ordinary skill in the art are capable, without undue experimentation, of operating an expert system to create

such a rule. In substantiation of this position, attached hereto is a copy of the results of a Medline search showing 40 "hits" for the term "expert system" in the context of medical diagnosis. Also submitted herewith are a copy of a home page for a commercially available expert system and, copies of United States Patent No. 4,658,370 and European Application 0 316 861. Both of those references disclose many details of expert systems in the context of medical diagnosis, and also provide many further references in the same context, thereby providing abundant evidence that those of ordinary skill in the art employ and rely on such expert systems routinely for medical diagnostic purposes.

A patent specification is entitled to presume and be based on knowledge possessed by those of ordinary skill in the art, and is not required to explain in detail concepts or features which are known to those of ordinary skill in the art. Given the evidence of the abundant use and knowledge of expert systems possessed by those of ordinary skill in the field of medical diagnostics, Applicants are unable to discern an information which is lacking in the present specification which would be necessary to enable a person of ordinary skill in the art to make and use the present invention as claimed.

Withdrawal of the rejection under §112, first paragraph, is therefore respectfully requested.

Claims 1-16 also were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for a number of reasons.

Claims 1 and 9 were rejected on the basis of the use of the terms "expert system" and "expert rules", however, as the above-noted attachments make clear, those terms are notoriously well-known and used by those of ordinary skill in the art,

and present no ambiguity whatsoever. The rejection under §112, second paragraph on this basis is therefore respectfully traversed.

Claims 1 and 9 also were rejected under §112, second paragraph because of the phrase "improved diagnostic value." This phrase has been changed in each claim to "improve diagnostic utility" and in view of the knowledge possessed by those of ordinary skill in the art as to the functioning of expert systems, this phrase is sufficiently definite. An expert system is a trainable system which, based on expert rules and incoming data which are being continually augmented, is able to refine or improve its output either to be more precise, or to become better adapted to the changing incoming data. In fact, an expert system which did not operate to produce an "improvement" in its output would be counterproductive. As described in the present specification, the "improvement" achieved in accordance with the invention is improved sensitivity or specificity (page 8, lines 12-14). Applicants would not object to using those terms in the claim language, however, it is believed that the generic term "utility" is equally satisfactory and definite.

Claims 1, 2, 9 and 13 were objected to because of the word "use" or "using" therein to refer to the expert system using the data compiled by the point of care sites and transmitted to the remote server at which the expert system is located. Independent claims 1 and 9 have been amended to state that the evaluation system is an expert system. As is clear from the above-noted attachments hereto, the fundamental basis for an expert system is that it "uses" expert rules and "uses" incoming data in order to formulate an output. The attached documents also employ terms such as "invoking" or "applying" or "employing" as alternative to "using" but the present Applicants do not see any significant difference among those terms. As set

forth in MPEP 2173.05(b), citing *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 758 F2d 613, 225 U.S.P.Q. 634 (Fed. Cir. 1985), if the claims, read in light of this specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, 35 U.S.C. §112, second paragraph demands no more. Applicants respectfully that the term “use” or “using” in the context of data and expert rules used by an expert system is as precise as the subject matter permits, and therefore the rejection of claims 1, 2, 9 and 13 on the basis of the use of the word “use” or “using” is respectfully traversed.

Claims 7 and 15 were rejected under §112, second paragraph because of the use of the phrase “augmented testing data” which the Examiner stated is vague and indefinite. The word “augmented” was used in those claims merely to give a name to the testing data being referred to in those claims, since the term “testing data” had already been used in previous claims. The term “augmented testing data” is therefore merely used to differentiate the data discussed in those claims from the “testing data” described in previous claims. Applicants submit that the content of “the augmented testing data” is clearly described within the context of each of claims 7 and 15, and the phrase “augmented testing data” merely gives a name to that data. This rejection is therefore respectfully traversed.

Claims 1 and 9 were also rejected under §112, second paragraph because the preamble of each of those claims referred to a method for evaluating medical data but the claims set forth a final step of “creating a new rule.” Those claims have been editorially amended so that the preamble is consistent with the final step.

Lastly, the phrase "new expert rule" in claims 1 and 9 was stated to lack antecedent basis, because the Examiner stated the phrase "new expert rule" implies the existence of an "old" expert rule, of which there is no mention in the claims. Claims 1 and 9 have been editorially amended to make clear that the expert system operates according to pre-existing expert rules, and that the "new expert rule" is created using all the data compiled from all of the point of care sites. Claims 1 and 9 are therefore submitted to be in compliance with all provisions of §112, second paragraph.

Claims 1, 2, 5 and 9 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of co-pending Application Serial No. 09/784,571. That application issued as United States Patent No. 6,484,104 on November 19, 2002. This rejection is respectfully traversed for the following reasons.

As noted above, independent claims 1 and 9 have been amended to specifically state that the data compiled by all of the point of care sites, and transmitted to the remote server at which the evaluation system (expert system) is present are used to create a new expert rule for the expert system. Claims 1-6 of United States Patent No. 6,484,104 merely state that an expert system is used in the context of a clinical study, but make no mention whatsoever of the creation of a new expert rule, on any basis or for any purpose. In view of the complete absence in claims 1-6 of United States Patent No. 6,484,104 of the creation of any new expert rule, Applicants respectfully submit that the subject matter of claims 1, 2, 5 and 9 of the present application would not have been obvious to a person of ordinary skill in

the art based on the content of claims 1-6 of United States Patent No. 6,484,104. Withdrawal of this provisional rejection is therefore respectfully requested.

Similar arguments apply to the rejection of claims 1, 5-7, 9, 14 and 15 under 35 U.S.C. §102(b) as being anticipated by Rindfleisch et al. The Rindfleisch et al. reference does not make any mention whatsoever of the creation of new expert rule and certainly provides no teaching to create a new expert rule for an expert system using data compiled from multiple point of care sites, as set forth in independent claims 1 and 9. The Rindfleisch et al. reference therefore does not disclose all of the elements of independent claims 1 and 9, and therefore does not anticipate either of those claims, nor any of the claims respectively depending therefrom.

Additionally, claims 1-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rindfleisch et al., in view of Evans. The Examiner relied on the Evans reference as disclosing an electronic medical records system wherein medical data are organized, sorted and managed in various different ways, according to various user-selected options. Although the Evans reference is directed to various ways for compiling and managing a medical reference database, there is no discussion therein of the use of an expert system for any purpose, and therefore even if the Rindfleisch et al. apparatus were modified in accordance with the teachings of Evans, a method wherein data compiled at multiple points of care sites were used to create a new expert rule for an expert system still would not result. Claims 1-16, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Rindfleisch et al. and Evans under the provisions of 35 U.S.C. §103(a).

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claim 1 as follows:

1. (Amended) A network for [evaluating] creating new expert rule in an expert system from medical data compiled in a clinical study, comprising:

- a plurality of disposable biochips respectively for a plurality of patients, each biochip containing a patient sample with multiple biomolecular markers;
- a plurality of point of care test devices respectively at a plurality of point of care sites, each point of care test device receiving at least one of said biochips, as a tested biochip, and performing diagnostic testing on the sample in said tested biochip to obtain a diagnostic result, said test device making said diagnostic result available at said point of care site and formulating raw point of care data including said diagnostic result and identification of the multiple markers in the tested biochip;
- a plurality of electronic patient records respectively for said patients;
- a plurality of point of care data entry stations respectively having access to at least one of said electronic patient records and respectively in communication with said point of care test devices, each data entry station including means for entering the diagnostic result from the tested biochip into the electronic patient record for the patient, as a tested patient, who provided the sample in the tested biochip, and for entering additional information selected from the group consisting of diagnostic data and patient history data from the tested patient into the

patient's electronic patient record, said diagnostic result and said additional information comprising clinical data;

a remote server and an evaluation system accessible by said remote server;

at least one data link between each point of care test device and each point of care data station, and said remote server, for transmitting said point of care raw data and said clinical data to said remote server; and

said evaluation system comprising an expert system operating according to pre-existing expert rules and creating a new expert rule with improved diagnostic [value] utility, composed to said pre-existing expert rules, using all of said point of care raw data and all of said clinical data.

Please amend claim 2 as follows:

2. (Amended) A network as claimed in claim 1 [wherein said evaluation system is an expert evaluation system operating according to expert rules, and] wherein said expert evaluation system [using] uses said new expert rule to devise a measurement protocol.

Please amend claim 9 as follows:

9. (Amended) A method for [evaluating] creating a new expert rule for an expert system from medical data compiled in a clinical study, comprising the steps of:

obtaining a plurality of samples respectively from a plurality of patients and storing the samples respectively in a plurality of disposable biochips, each of said samples including multiple biomolecular markers;

providing a plurality of point of care test devices respectively at a plurality of point of care sites;

respectively receiving said biochips in said point of care test devices, as a tested biochip, and in each point of care test device performing diagnostic testing on the sample in the tested biochip to obtain a diagnostic result;

making the diagnostic result available at the point of care site;

formulating raw point of care data in each point of care test device including the diagnostic result and an identification of the multiple markers in the tested biochip;

providing a plurality of electronic patient records respectively for said patients;

entering the diagnostic result into the electronic patient record for the patient, as a tested patient, who provided the sample in the tested biochip into the electronic patient record for the tested patient together with additional information selected from the group consisting of diagnostic data and patient history data, said diagnostic result and said additional information comprising clinical data;

providing a remote server at a location remote from said point of care sites;

supplying the raw point of care data and the clinical data from all of the point of care sites to said remote server; and

at said remote server, entering said raw point of care data and said clinical data from all of said point of care sites into an expert system operating according to pre-existing expert rules and, in said expert system, creating a new expert rule with improved diagnostic [value] utility, compared to said pre-existing rules, using all of said raw point of care data and all of said clinical data.

Please amend claim 10 as follows:

10. (Amended) A method as claimed in claim 9 wherein the step of creating a new expert rule comprises creating a new expert rule for devising a measurement protocol.

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(54) **Hematology-diagnosis apparatus employing expert system technology.**

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Note : Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

Field of the Invention

This invention relates to hematology-diagnosis apparatus, that is apparatus which on the basis of instrument-obtained hematological data fed into the apparatus, retrieves from memory storage diagnostic and hematological information, and makes a record thereof available to the hematology specialist (hematologist) or even the general practitioner physician. As will be seen hereinafter the apparatus employs computer/data processor technology, and more particularly expert system technology which is a branch of the technology commonly known as artificial intelligence.

The terms "hematological" and "diagnostic" are used in broad and somewhat overlapping sense at this point; subsequently, in the description, distinction will be made between "hematological reminders" or "hematological messages", and "diagnostic reminders" or "diagnostic messages"; see for example Appendix 1 which presents some typical diagnostic printouts. Appendices will be referred to throughout this text; they are found at the end of the text. As will be seen hereinafter, at the location reserved for "diagnostic reminders" there will occasionally appear messages which decline to present a diagnosis in the truest sense of that term, or even messages termed "technical alerts" which indicate presence of actually, or possibly, invalid input data. These messages, because of their appearance at "diagnostic reminders", will be considered "diagnostic" for some purposes hereinafter. By the same token, a message intended to appear at "hematological reminder" will be deemed to be a "hematological message", even if it seems to be somewhat of a diagnostic nature.

Through this text references will be made to a Bibliography which appears towards the end of the Detailed Description; items are indexed there as BI 1 (read as: Bibliography. Item 1), BI 2, BI 3 etc. Throughout the description the reference will be made typically, merely as BI 1.

The hematological/medical terminology used in this text, follows rather closely the terminology presented in BI 1 and BI 9 to BI 13. The artificial intelligence/expert system terminology utilized in this text follows closely the terminology presented in BI 2, especially its Glossary; see also BI 3 to BI 6. It has been stated above, that "hematological data" are fed to the apparatus; in this text, "hematological parameters" or simply "parameters", or "hematological arguments" or simply "arguments" are used interchangeably with "hematological data". "Messages of hematology-diagnostic significance" is used occasionally as generic for "hematological" and "diagnostic" messages.

For brevity, hereinafter "apparatus of the invention", "system of the invention", will be referred to respectively as "Apparatus", "System".

Background of the Invention

Speaking as of the middle 1980s, hematological diagnostics is still practiced largely by the time-honored approach of lookup in authoritative works such as BI 1, or else the hematologist or physician depends upon his own memory. Either way, the approach is mental. As will be seen hereinafter, the hematological parameters which are processed by the Apparatus are four in number, they will be referred to throughout this description as P H G L; these are abbreviations for Platelet Count, Hematocrit, Granulocyte Count, Lymphocyte/Monocyte Count. Alternative abbreviations for these are PLT, HCT, #GRANS, #LYMPH. The mental approach operates on the same, or similar parameters, or on parameters some of which are in the quartet just stated or similar thereto, plus other kinds of input data, depending on the instrument-type or data source. The mental approach will now be discussed, assuming it is based on P H G L data, but the discussion is most general.

The parameters P H G L are presented to the "mental processor" (or the Apparatus) as numerics. The mental approach is by a method known in scientific or mathematical fields as trial-and-error method. On the basis of the quartet of parametric data on hand, the physician assumes that certain trial hematologic/diagnostic conditions or conclusions - plural ones (rather than just one single one) are quite common - apply to the quartet, and hence to the patient in question. Next comes lookup to see if the assumption is correct. If incorrect, another trial assumption is made, and the lookup is repeated. When eventually an assumption proves to be true or a "hit", the mental processor must continue to make trial assumptions, in order to be sure to reach all of the possibly plural "hits". For a physician who is quite experienced at this, the convergence of the process to the first correct conclusion, may be fairly rapid, because he or she will not likely assume - as an inexperienced physician might assume - a trial condition for which the given quartet of parametric numerics is far afield. Nevertheless, the trial-and-error process is too time-consuming, and is conducive to physician's diagnostic error of commission (because of fatigue, for example) and of omission (plural conclusions to be drawn).

To alleviate this situation, efforts have been made to automate hematology-diagnostic processing. Before considering this, there now follows a brief view of automated systems, and in particular expert systems, di-

rected to medical diagnostics, that is to the many fields of medicine including hematology, general medicine, and internal medicine.

The number of separate, individual, previously proposed systems directed to automated medical diagnostics is quite sizeable, but for the most of these just one single unit has been constructed; in some instances a second unit has been constructed as an improvement or modification of first unit, and no more beyond that. As to hematology diagnostic systems previously proposed these are very few in number; only two have received significant publicity in the literature, and here too, for each of these two, one unit was constructed without further duplication. Then reasons for such one-unit construction, for hematology diagnostics will be presently discussed, and they apply also to general medical diagnostics.

The literature devoted to general medical diagnostic expert systems is quite extensive; BI 2 describes some and lists others in its own bibliography; indeed surveys or listings of these systems have been prepared, some with brief summaries devoted to each listed system; see BI 6 to BI 8 and BI 12.

As to hematology-diagnostic systems, their number is quite limited. One better-known system called HEME (see BI 9 to BI 12) produced a computer program which used a probability approach to assist in the diagnosis of general hematologic disease. HEME was presented as a series of papers by Cornell University/International Business Machines (IBM). The development and operation of HEME spanned a time period of about 15 to 20 years. HEME was intended to operate as a continuously self-improving system. It was utilized chiefly as a research tool, and as a training device for student-hematologists. As is indicated in BI 11, pages 764, 765, HEME received little use for various reasons stated thereat.

The other better-known hematology-diagnostic system is ANEMIA which is described in BI 13. ANEMIA is an Italian-originated computer program which is designed to assist in the diagnosis of the anemia. Like HEME, ANEMIA was operated at a research center, and did not progress beyond that stage.

HEME and ANEMIA were far too complex to be used by physicians who are not also computer experts. The two systems were interactive (see BI 2), meaning that in order to develop a diagnosis, the user had to interrogate the system sequentially so and repeatedly, with the system providing answers in several tiers of interrogation. Of course, interactive systems have certain advantages in certain applications, but they are not too well-suited for the small-office practitioner. As will be seen hereinafter, the System of this invention is non-interactive; the user of the System needs very few skills in operating the system which essentially takes care of itself in a "one-shot-operation".

The user of the previously proposed medical diagnostic expert systems had to be well-versed in the cryptic computer-code language, to intercommunicate both way with the apparatus. In contrast, in the System of this invention, intercommunication is in human language in narrative sentence form, or in the so-called short mode, in short-slogan-type word arrangements, also expressed in simple human language.

US-A-4 290 114 discloses a general computer-aided health care system for use by a paramedic. Findings taken from the patient by the paramedic are assigned numerical codes by use of preprinted forms. The paramedic uses a keyboard to enter the numerical codes into a fixed-purpose computer. The computer compares the findings with a number of disease definitions stored in its memory. The computer then operates a printer to list numerical codes for all treatments to be administered. The paramedic uses these codes to enter a treatment and diagnostic manual which gives the name of the disease and specific instructions for its treatment, in the language of the paramedic.

Object of the Invention

It is a general object of the invention to alleviate and to minimize the problems encountered in processing of hematological data.

It is another object of the invention to provide computer-based expert-level assistance to the physician in interpreting hematological data.

It is still another object of the invention to provide hematology-diagnosis apparatus which employs expert level hematology knowledge.

A still further object of the present invention, is to provide such hematology-diagnosis apparatus in a non-interactive arrangement which is easily operable, does not require extensive training in computer technology, and requires little or no human entry of data, and which provides readout expressed in human language.

Introduction to the Approach of the Invention

It has been stated hereinabove that the system operates on the basis of four hematological parameters HPGL, and their respective numerical input values. It should be noted that HEME (BI 9, page 588) and ANEMIA (BI 13, page 17) also operated with some of the same or similar hematological parameters, but these systems

used many more additional "findings" or input data; for example HEME could operate on as many as 585 findings. The system is based on operation on the basis of just a small number of parameters, and this number is kept constant. This leads to simplicity in operation, internally of his apparatus, and also as far as the user is concerned. In the Apparatus, for each one of the four parameters, subdivision into respective ranges of its numerics is made; these ranges are termed Clinically Important Intervals or CII's. In HEME (see BI 9, page 588), such a subdivision into ranges (for some of the hematological parameters), was also made, but apparently by the physician-user; in the system, the subdivision is made internally, and automatically. However, and as will be seen in the next Section the impact of automatic subdivision is even more dramatic. In the System, H is given twelve CII's, P has eight, G has ten, and L has eight CII's (see Appendix 2). The number of possibly coincidences of these four sets of CII's -- all ranges taken into account -- equals $12 \times 8 \times 10 \times 8 = 7680$. However, the total number of messages (hematologic and diagnostic) is, speaking as of late 1986/early 1987 only approximately 70. By a unique approach, discussed in the next Section, the Apparatus, instead of scanning 7680 possibilities or setting up 7680 AND conditions, scans or sets up merely the approximately 70.

Before proceeding to the next Section, it should be noted that HEME (cf. B19) and ANEMIA (cf. BI 13), and indeed most of the general medical, diagnostic systems, were so-called "rule-based" expert system (cf. BI 2 for explanation). Also known in the field of artificial intelligence are "frame-based" expert systems (cf. BI 3).

Approach of the Invention - Simplified Statement

The System has some resemblance to rule-based systems and to frame-based systems, but only insofar as the end result is concerned. The scheme of this System, in operating on the input parameters to arrive at the output printout, is unique. Briefly stated here the scheme of this System is to allocate approximately 70 positions -- these are space-positions insofar as locations in memory is concerned, but also time positions, for scanning --, to the approximately 70 possible hematologic and diagnostic messages, or more accurately to their respective 70 one-bit identifiers. One preselected bit-string or bit-stream of these positions, is formed for each one of the four parameters H P G L, H has twelve bit strings available, but the preselected one is predicated on the particular H input numeric or argument on hand, and similarly for P G L. Alignment, in one particular position, of all binary ones in the four bit-strings, results in "success" or "hit", and often multiple hits are achieved for the hematological messages, or the separately printed out diagnostic messages, or both. The "hit" hematological and diagnostic messages or reminders are fetched out of memory, and are printed out. The Statement of this paragraph is somewhat simplified, and will be amplified subsequently.

Summary of the Invention

In accordance with the invention as claimed, the Apparatus comprises a computer, which for example may be a personal computer, and as such is provided with its usual memory facilities, a central processing unit and peripheral devices such as a printer and viewing screen. Stored in the memory facilities is the so-called knowledge base (cf. B 12) applicable to hematologic diagnostics, and instructions by which the Apparatus is to process the input data. The Apparatus also includes means for entering the input data into the Apparatus. The Apparatus accordingly executes the instructions, and prints out the applicable hematological and diagnostic messages.

More detailed aspects of this summary will be presented in the subsequent description. One such aspect has been presented under the heading Approach of the Invention - Simplified Statement. That simplified statement will be amplified subsequently.

Some of the advantages of the invention have been discussed above, and others will be discussed in the Conclusion of the specification.

Brief Description of the Drawings

Other objects, advantages, and features of the invention, as well as variations thereof, will be apparent from the following, more detailed description when considered together with the accompanying drawings, in which

- Figure 1 is a block diagram of computer or data processor apparatus with which the present invention may be practiced;
- Figure 2 is a block diagram of the internal structure of the computer of Figure 1;
- Figure 3 is a block diagram of the expert system of the invention incorporable in the apparatus of Figures 1 and 2; and
- Figure 4 is a flow diagram illustrative of the sequence of events performed by the apparatus to result in

the output of the hematology diagnostics.

Detailed Description of Preferred Embodiment

5 Introduction

The invention will be described, by way of example, under the assumption that the numerics for the parameters H P G L have been obtained as measured or indicated by a hematology system manufactured by Becton Dickinson and Company, hereinafter occasionally referred to as Becton Dickinson or simply B-D, of Franklin Lakes, New Jersey 07417, USA, and more specifically the Clay Adams Division of that Company, also of Franklin Lakes, New Jersey 07417. Becton Dickinson is the assignee of the present invention. That B-D System is known as the QBC II Centrifugal Hematological System. QBC is a Registered Trademark of Becton Dickinson and is an acronym for Quantitative Buffy Coat. The latter system will be briefly referred to as the QBC II System; it will be briefly explained here. However, it should be understood that the present invention could be practiced by processing hematologic parametric data obtained from other systems or other instruments, or even on the basis of calculated hematologic parametric data, whether calculated by machine or humanly so.

The QBC II System is described in literature available from the manufacturer; refer to BI 14 to BI 17. Aspects of the QBC II are described in professional journal literature; see BI 18, BI 19. Briefly stated here, the QBC II System includes preparation of an examinee's blood specimen or assay in a special blood-tube, known as buffy coat analysis tube (see BI 14 to BI 17; BI 19), placing this tube in a centrifuge and subjecting it to centrifugal action as described in BI 14, BI 16, BI 17, see also BI 18; and then emplacing the tube in an instrument termed QBC II (the QBC II proper) and positioning it on the instrument in six (for venous blood) or seven (for capillary blood) discrete positions, as described in BI 16 to BI 19. The QBC II instrument proper produces visual numeric indication, not just of the four parameters H P G L, but three additional numeric parameters indications, for a total of seven. The three additional parameters will be discussed below.

The QBC II instrument visual indication is by means of a display, on the instrument panel, produced by light-emissive-diodes. Additionally, and optionally, a computer-printer, such as Epson, Model LX 86 may be plugged into the QBC II instrument and the seven-parameter numerics will also be printed. For the purposes of this description, it may be assumed that as a minimum, the H P G L numerics have been provided to the user of the System of the present invention, by personal reading of the QBC II instrument, or by his or her reading the instrument-printer's printout currently as the printout is being made, or reading it at a later time, or by communication to the operator currently or later by voice or in writing, or electronically. The System will re-compute and print out the three additional parametric numerics, whether the operator initially knew their values or not.

The QBC II instrument displays, and its printer prints the numerics for the altogether seven parameters. The system of the invention reprints all seven, although it receives as inputs only the four mentioned H P L G. Such a reprint is shown in Appendix 1. As seen there, H is expressed as percentage, whereas P L G are each expressed in $\times 10^9/L$, or multiply by $10^9/L$. A fifth parameter, W B C or Total W B C (White Blood Cell Count) is also expressed in $10^9/L$. The sixth and seventh parameters indicate Percent Granulocytes and Percent Lymphs + Monos, respectively. Thus, the latter two are related to the parameters G and L previously discussed.

It has been stated above, that the present invention may be practiced with a personal computer, and it will be described in that manner.

Figures 1, 2

Referring to Figure 1, shown there is a computer (CPTR) or data processor 10 which may be assumed to be a personal computer, for example IBM PC Model AT. The computer 10 is equipped with the usual peripheral devices, namely a cathode ray tube (CRT) monitor or screen 12, and printer (PTR) 14, which for example may be Epson printer, Model LX 86. The computer 10 is further equipped with the usual keyboard (KBD) 16, and a receptacle 18, in which a memory storage device, such as a magnetic "floppy disk" 20 is received. It may be assumed that the computer 10 has been pre-conditioned, to PL/M-86 language; that language is explained in BI 20. The floppy disk 20 stores the knowledge base of the expert system; "knowledge base" is used in the sense of BI 2 and BI 4. As applied to the expert system hereunder consideration, knowledge base will be detailed below. Suffice it to state here, the knowledge base embraces the mass of hematological/diagnostic knowledge of the kind presented in BI 1, from which mass of knowledge there is to be extracted the particular knowledge applicable to the four parametric numerics H P G L obtained from the hematological instrument, for example the QBC II, or else obtained by calculation. The disk 20 further stores the "inference engine" -- usage of this term is also as in BI 2 --; broadly stated at this time, inference engine implies the processing, by

the Apparatus, on the basis of the four parametric numerics, as applied to the knowledge base, to produce the applicable diagnostic printouts of the kind shown in Appendix 1.

The disk 20 in place shall be assumed to be part of the memory storage of the computer 10. The keyboard 16 is used by the Operator to enter the four basic parametric numerics for H P G L. Basically, the operator will enter via the keyboard 16 merely the four numerics; the printer 14 will subsequently print, side-by-side to the same numerics respectively, descriptive phrases of the kind shown in the examples of Appendix 1. Following the entry of the four numerics, the operator will follow this by depressing either the letter-key "S" or the letter-key "L". "S" implies the "short mode" and further implies a command to the Apparatus to execute in the short mode. "L" analogously implies selection of the "long mode" and a command to the Apparatus to execute in the long mode. Appendix 1 includes examples of short-mode, and long-mode presentation; more on these examples under the heading "The Expert System" (Figure 3; Appendix 1); also, more on the manner of discrimination between "L" and "S" execution of the system, below. Depression of "S" or "L" being also an "execute" command, the system proceeds to print out documents of the kind shown in Appendix 1.

Referring to Figure 2, the computer 10 is shown in block form with the usual internal equipment associated with this type of personal computer. Its memory storage facility, in addition to the disk (DK) 20, includes a random access memory (RAM) 22 and a read-only-memory (ROM) 24. It will be appreciated that the memories 22 and 24 could each be considered in plural stage or group form rather than necessarily being a sole unit. For the disk 20 there is provided the usual disk drive (DDR) 26. The computer 10 further includes the usual central processing unit (CPU) 28 which performs the processing required by the present invention, that is the processing required by the "inference engine" to be presently discussed with reference to Figures 3 and 4. Such processing also includes some operations which are arithmetic-type computations in the truest sense. Finally, the computer 10 includes input-output units (I/Os), or interfaces 20.

THE EXPERT SYSTEM (Figure 3; Appendix 1)

Referring to Figure 3, the expert system is assigned reference numeral 100. It is composed of two major sub-blocks, namely the knowledge base 102 and the inference engine 104. The general definitions given for knowledge base and inference engine should be continued; elaborations thereon will be given below. As shown in Figure 3, the general flow is four parametric numerics ingoing into the inference engine 104, and also knowledge base information ingoing to the inference engine 104. Outgoing of the inference engine 104 are printouts of the kind shown in Appendix 1. Additional consideration of the latter printouts, at this point, is useful in preparation for the further description of Figure 3, and also of Figure 4.

For Appendix 1, dual identification of pages is used. The pages are numbered consecutively by 1.1, 1.2, 1.3 etc. Secondly, the pages are identified by hematocrit (H) value, and "short mode" (S) or "long mode" (L). The meaning of these modes will be explained below. Typically for other pages, the identification of Appendix pages 1.1, 1.2 are H 40/S and H 40/L respectively.

Appendix page 1.1 (H 40/S) is applicable to a patient exhibiting all hematologic values within normal limits. This page indicates three kinds of so-called reminders which form part of the knowledge base 102. Side-by-side to the reprinted four basic numerics for H P G L are "descriptive" reminders, also termed "qualitative reminders" and sometimes termed "descriptors" or "qualitative phrases". ANEMIA (see BI 13, page 17) generated similar descriptors, in a somewhat differing context. Indicated next on Appendix page 1.1 is a second kind of reminder, there given as "General Hematologic Clinical Reminders", or simply hematologic reminders. Next follows a third kind of reminder, given on Appendix page 1.1 as "Diagnostic Considerations", or simply diagnostic reminder.

Digressing briefly from Appendix 1, the fourth kind of reminder, termed "subcase reminder" will under certain circumstances appear as subordinate to the hematologic reminder or the diagnostic reminder. This happens when the hematologic or diagnostic reminder embraces a rather broad range, whereas the subordinate subcase reminder applies to a narrow range which lies within the broader range, and that narrow range is applicable to the patient.

Reverting again to Appendix 1, page 1.2 (H 40/L) is a long-mode printout; its four H P G L values are respectively the same as those of H 40/S and apply to the same patient. Similarly, Appendix 1 pages 1.3 and 1.4 (H 53/S and H 53/L) apply to one and the same patient. From here on a single printout (short or long mode) per quartet of H D G L numerics, will be given in some instances. On pages 1.2 (H 40/L) and 1.4 (H 53/L) the reminders appear as "complete messages"; each complete message consists of "header" and "body" of message. On pages 1.1 (H 40/S) and 1.3 (H 53/S) merely the headers are shown. Note on pages 1.3 and 1.4 (H 53/S and /L) the presence of multiple, and in this instance two hematologic reminders. This implies multiple (two) "hits" or "successes" in the sense of the specification introduction, as will be more fully elaborated in the description of Figure 4.

Another exemplary printout, is presented in Appendix page 1.5 (H 49.9/S). The diagnostic reminder thereat is unusual in that: (1) at the location where one would expect a "header", there appears a statement which more nearly resembles a "body", but should be construed as a header. In the corresponding long-mode version (not shown), exactly the same diagnostic reminder would appear. The System declines to give a diagnostic reminder (in the truest sense) on the basis of the HPGL values, and suggests more testing. More on this specific reminder at "Miscellaneous Matters" (conclusion of description).

In regard to the discrimination, by the Apparatus, in presenting headers only for short mode, but headers and bodies in the long mode, this is accomplished as follows. The hematologic and diagnostic reminder messages are stored in memory, in an arrangement such that the header information, stored in bytes (1 byte = 8 bits), is concluded with an artificial byte, which in turn is followed by "body" bytes which conclude with an end-of-message byte. The artificial byte is a pseudo-end-of-message byte. It is interpreted as the end-of-message in short mode, so that the message retrieval ends at the end of the header. In long mode, the System ignores the artificial byte, and continues on its retrieval through the body of the message, to the true end of the message.

The Knowledge Base - Continued (Figure 3)

Refer again to Figure 3 for further consideration of the knowledge base 102. Part of the knowledge base is the definition or demarcation of the boundaries of the CII's (clinically important intervals). This is shown in Appendix 2 - CII Summary. That Summary is organized, in the first instance, by the four parameters H P G L, and then individually for each, the respective CII's assigned to it. Thus, H is assigned twelve CII's or ranges, P eight, G ten, and L eight, as had already been indicated in the specification introduction. The tabulation for H is typical also for the other parameters; for each CII the applicable hematocrit range is shown, plus the descriptor or descriptive reminder, previously mentioned.

The knowledge base block 102, following "CII Boundaries" lists the Reminder Types -- these have been described above --; also Priority Information, Applicable and Null Domains -- these will be discussed; and finally reminder Texts -- these have been discussed with reference to Appendix 1; further aspects of the reminder texts will be discussed under the next heading.

The Knowledge Base -- Continued

It has been stated previously, in the specification introduction that the number of messages is about 70, and this number embraces both the diagnostic messages and the hematological messages. More accurately, and speaking as of 1986/1987, the number stands at 69; the system approach is to assign the number sequence 0 to 68, rather than 1 to 69. Incidentally, concerning the previous discussion of multiple (rather than single) messages, these multiple messages are intended to apply within one and the same rubric, either hematologic or diagnostic. Thus, in the example given on Appendix page 1.1 or 1.2 (H 40/S or /L) there is just one single hematologic message and one single diagnostic message. However, these two reminders stem from separate ones in the series 0 to 68, and more specifically from No. 13 for the hematologic reminder, and No. 53 for the diagnostic reminder. Correspondingly, these two messages will be stored at separate locations in memory. The diagnostic reminder of Appendix page 1.5 (H 49.9/S) is not contained in the series 0 to 68; see "Miscellaneous Matters."

Figure 4

Reference is now made to Figure 4 which is an operational flow chart for the System. Recall, in connection with the description of Figures 1 and 2 that the operation is initiated by entering the four parametric numerics via the keyboard 16 and selection of the long mode by entering the letter L, or the short mode by entering the letter S. In consequence, the System begins to execute the instructions stored in the memory facilities, by determining the CII's of the four parameters or arguments H P L G which are applicable to the four input numerics, as represented by the block 202 in Figure 4. This step might also be termed a preselection of the applicable CII's; referring to Appendix 2, that one of the twelve available CII's for H is selected which is applicable to the H value of the input numeric, together with its descriptor (see Appendix 2), and similarly for the remaining three parameters or arguments P G L.

In the next step, (block 204) the indication "output" implies "prepare for printout." The just-entered four numerics, together with the descriptive phrases (Appendix 2) -- just fetched out of memory --, are prepared for printout.

The next block 206 calls for retrieval of "Reminder Sets for Input CII's." The retrieved reminder sets are

four in number, namely one for the applicable CII for each respective parameter H P G L. The set is a selection of all those numbers from the sequence No. 0 to No. 68 which applied to the selected CII in question.

In Appendix 5 are shown the declarations for the twelve possible CII's for H; then those for the eight CII's for P; then those for the ten for G; and then the eight for L. The numbering given for the CII's begins, in each instance, with one (1). On the other hand, the numbering of the reminder set Nos. and their relative columnar positions, begins with zero (0). The CII presentation of Appendix 5, and indeed the remaining contents of Appendix 5 are stored in the memory facility of the system as part of the knowledge base.

In Appendix 5 each CII is arranged as a bit string which in turn is arranged as nine bytes; the numbering of these bytes, for the purposes of the present discussion, begins with one (1). The bytes are arranged in binary format; since there are eight bits per byte, a total of $9 \times 8 = 72$ columnar positions are available; numbering, for purposes of this sentence and the next sentence begins with one (1). The seventy-two positions adequately accommodate the sixty-nine reminder sets defined in Appendix 3 in the sequence 0 to 68; recall that this sequence (and hence the columnar positions) do not embrace the diagnostic reminder message of Appendix page 1.5, (H 49.9/S); see "Miscellaneous Matters". For the next ensuing discussion, it will be convenient to continue in terms of byte numbering from one to nine and of the CII numbering from one to twelve (for H, and typical for others). The numbering of the available columnar positions will be deemed to run from 0 to 71, with a progression from left to right, and the numbering of the bit positions within a byte, extending from 0 to 7, with the progression from left to right. Following the bit position seven, each byte terminates with suffix-letter B which stands for binary (rather than, for example, D - decimal). However, even "binary" should be construed with some caution; consider the first or left-most byte in CII No. 1 for P. This byte reads 11111111; this should not be construed to mean a numeric value of 255 (decimal expression). Rather, the suffix-letter B implies that each one of the bit-positions of this byte contains a binary 1, or is "set" or is "up" or "on".

Only those bit-positions which are set, possibly qualify for retrieval of the related reminder set (Appendix 3); in any position where binary 0 ("reset" or "down" or "off") appears, retrieval is inherently disqualified.

Reverting to Table 2, above, and also scanning left-to-right the CII 6 for H in Appendix 5, the reader will arrive at bit-positions which correspond numerically to the reminder set Nos. appearing in Table 2. In operation, and referring again to the block 206 of Figure 4, the System will retrieve from memory, for H, its CII 6, and as per the example of Table 1, for P its CII 5, for G its CII 5, and for L its CII 4; the formats for these CII's are as shown in Appendix 5.

The next step is shown in block 208 of Figure 4. The System computes the intersections of the reminder sets; this is done by executing the logical AND function, bit-position by bit-position in the successive columns for the four applicable parametrics CII's. To survive for possible further qualification for printout it is necessary that a binary 1 appear in each one of the four applicable CII-representation in a given column. The System (block 210, Figure 4) next eliminates or excludes reminders for which the applicable input CII's are in null-domains. As has been stated previously, exclusion of a reminder by null-domain inhibition also requires presence of logical AND condition in the four applicable CII's.

Processing now continues on a basis of the characteristics applicable to the remaining reminders Nos.. In the next step, block 212 of Figure 4, the remaining reminders are classified as to type, namely hematological, diagnostic, or subcase. Supplementing the previous statements regarding subcases, it is remarked here that subcase reminders may arise in conjunction with either hematological reminders or diagnostic reminders. The subcase reminder will be printed immediately after some particular hematological or diagnostic reminder of which it is a subcase.

The next two steps are represented by the blocks 214 and 216 of Figure 4. The step or block 214 calls for computing parameter weights; the step or block 216 calls for computing priority ranking of hematological reminders. These two steps have been described in connection with a description of Figure 3, and the knowledge base. Supplementing that previous discussion the actual dominant factor data is stored in a memory location which is specified by a data declaration arranged in an array of bytes in hex format (BI20) where each byte contains the dominant factor information for the respective reminder message. The dominant factor information is encoded in the four bits of the upper nibble (1 nibble = one half byte) of each byte as follows: H: bit 7; P: bit 6; G: bit 5; L: bit 4; numbering descends from 7 to 0 (total: eight).

If the bit is set, that parameter is dominant for the respective reminder message. As has been pointed out previously the reminder message may have more than one dominant parameter. Attention has also been directed to reminders without dominant parameters.

The System, in proceeding from step 214 to step 216 and ultimately to step 220 (Compute Priority Ranking of Diagnostic Reminders), inherently makes its own priority selection as between all remaining hematological reminders (plus their subcases) on the one hand -- these are preferred --, and all remaining diagnostic reminders (plus their subcases) on the other hand. This is on the basis of the reminder-type indication.

In the next step or block 218 (Figure 4) the remaining hematological reminders and any subcases are fully

retrieved, prepared for printing ("output") and in the priority order decided upon in the step 216.

The steps 220 and 222 are analogous to the steps 216 and 218, but apply to the diagnostic reminders and their subcases. As to the processing of the diagnostic reminder of Appendix page 1.5, see "Miscellaneous Matters." As the final step 224 the System prints out all "outputs" in the order 204, 218, 222, in either short mode or long mode, and with priority ranking as described for the steps 216, 220. In regard to the "output" steps 204, 218, 222, and the printout step 224 the System locates by way of a "lookup table" the memory addresses which correspond to the reminder texts to be printed out. Although there is a numerical correspondence of message numbers (total 69; numbering begins with one) and memory addresses, yet the memory stores much other information besides the messages, and accordingly has a much greater number of addresses.

Miscellaneous Matters

Regarding the diagnostic reminder message of Appendix page 1.5 (H 49.9/S) it will be recalled that the message attempts no diagnostic indication in the truest sense. Additionally, the message is not retrieved in the step 206 (Figure 4), nor is it prepared for printout by the steps 220, 222 of Figure 4. Instead, applicability of the message is ascertained "in default" of any other diagnostic message at step 212, and thereupon at step 222, the Appendix page 1.5 (H 49.9/S) message is retrieved from a special location in memory. Considering that this message occurs rather frequently, the just discussed handling is simpler than handling in the same manner as the other messages.

Technical Alerts

Technical alerts are messages which indicate invalid combinations of HPGL numerics, some indicated to be unconditionally invalid, others merely possibly likely to or conditionally so. It should be noted that ANEMIA (BI 13, page 19) monitored input data for invalidity. An important feature of the System is that the technical alert suggests the likely error by the human operator which induced the invalid instrument readings.

Modifications

The described system admits of various modifications. For example, the number of stored messages could be readily increased.

Some potential user-physicians have indicated a preference for printing out diagnostic messages before hematologic messages. This is readily achieved by interchanging the priority of the designator, D over H, in the sense of the flow in Figure 4. Hand-in-hand with this modification is a proposed modification to single out technical alerts (designator T) as a separate grouping of messages, apart from diagnostic and hematologic messages, and give them highest priority. This too is readily implemented following the previously given teachings.

Conclusion

From the foregoing it is seen that by the present invention there has been provided a practically useful hematology diagnostic system. Among its advantages are:

Human language presentation, input and output. This is in contrast to the prior schemes which employed cryptic computer-type coding which led to commission of errors by non-computer trained physicians.

Operability on the basis of consistently the same number, and same small number of that, and the same kind of input parameters (HPGL) with their numerics all obtained from a single data source (QEC II). This has led to simple equipment which may be installed and readily used in many physicians' offices. This is in contrast to the prior systems, of which only one of its kind was made available at a university research center, there to serve the world at large.

A noninteractive expert system is used. This has the decided advantage that advice is given to the physician in "one shot", rather than the mutual repeated interrogations required by prior art approaches. The user of the system need not be a computer expert.

The System does not forget important information, does not become tired, distracted or rushed, and so provides a consistently high quality interpretation of numerical results.

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Appendix 1

Hematocrit (%)	= 40 normal value for adult males: 40-54%
	normal value for adult females: 37-47%
Platelets ($\times 10^9/L$)	= 254 within normal range
Total WBC ($\times 10^9/L$)	= 8.0
Percent Granulocytes (%)	= 62.2
Granulocytes ($\times 10^9/L$)	= 5.0 within normal range
Percent Lymphs+Monos (%)	= 37.8
Lymphs+Monos ($\times 10^9/L$)	= 3.0 within normal range

GENERAL HEMATOLOGIC CLINICAL REMINDERS:

THE REPORTED HEMATOLOGIC VALUES ARE WITHIN NORMAL LIMITS FOR ADULTS.

DIAGNOSTIC CONSIDERATIONS AND WARNINGS:

NORMAL.

5	Hematocrit (%)	= 42.0 normal value for adult males: 40-54%
		normal value for adult females: 37-47%
	Platelets ($\times 10^9/L$)	= 340 within normal range
	Total WBC ($\times 10^9/L$)	= 6.0
	Percent Granulocytes (%)	= 67
	Granulocytes ($\times 10^9/L$)	= 4.0 within normal range
10	Percent Lymphs+Monos (%)	= 33
	Lymphs+Monos ($\times 10^9/L$)	= 2.0 within normal range

GENERAL HEMATOLOGIC CLINICAL REMINDERS:

15 THE REPORTED HEMATOLOGIC VALUES ARE WITHIN NORMAL LIMITS FOR ADULTS.

The reported hematologic parameters are within normal limits. This does not rule out the presence of disease. If the detection of eosinophilia is clinically important, an examination of the peripheral smear should be performed. The results, especially the hematocrit, should be compared to baseline values for the patient in order to discover changes from earlier findings. The normal hematocrit values for adults, 40-54% for males and 37-47% for females, are determined for patients at sea level; at higher altitudes add 2% for each 4000 ft. (1200 meters). In infants and children the normal hematocrit values are higher than in adults for the first two months of life, lower afterwards and gradually rise until puberty. Wintrobe, M.M.: Clinical Hematology, Ed. 8, pp. 1885, 1888, 1893, 356, 372.

25 SPECIFIC DIAGNOSTIC CONSIDERATIONS INCLUDE:

NORMAL

The reported hematologic values are within the adult normal range.

30	Hematocrit (%)	= 53 normal value for adult males: 40-54%
		normal value for adult females: 37-47%
	Platelets ($\times 10^9/L$)	= 247 within normal range
	Total WBC ($\times 10^9/L$)	= 28.5
	Percent Granulocytes (%)	= 15.1
	Granulocytes ($\times 10^9/L$)	= 4.3 within normal range
35	Percent Lymphs+Monos (%)	= 84.9
	Lymphs+Monos ($\times 10^9/L$)	= 24.2 extremely elevated

GENERAL HEMATOLOGIC CLINICAL REMINDERS:

40 LYMPHOCYTOSIS/MONOCYTOSIS.
MILD OR BORDERLINE POLYCYTHEMIA (ERYTHROCYTOSIS).

DIAGNOSTIC CONSIDERATIONS AND WARNINGS:

45 LEUKEMOID REACTION (LYMPHOID TYPE).

	Hematocrit (%)	= 53 normal value for adult males: 40-54%
		normal value for adult females: 37-47%
	Platelets ($\times 10^9/L$)	= 247 within normal range
	Total WBC ($\times 10^9/L$)	= 28.5
50	Percent Granulocytes (%)	= 15.1
	Granulocytes ($\times 10^9/L$)	= 4.3 within normal range
	Percent Lymphs+Monos (%)	= 84.9
	Lymphs+Monos ($\times 10^9/L$)	= 24.2 extremely elevated

55 GENERAL HEMATOLOGIC CLINICAL REMINDERS:

LYMPHOCYTOSIS/MONOCYTOSIS.

increases in lymphocytes/monocytes may be due to (a) infectious mononucleosis (b) certain acute infections

tions (e.g., pertussis, infectious hepatitis, and cytomegalovirus infection) and certain chronic infections (e.g. tuberculosis, brucellosis, secondary and congenital syphilis), (c) certain protoicaf inf ctions, (d) some lymphomas and in certain acute leukemias (blast cells may enlarge the lymph/mono layer) and (e) chronic lymphocytic leukemia. Addition tests include an examination of the peripheral smear and those suggested by review of history and physical examination. Wintrobe, M.M.: Clinical Hematology, Ed. 8, pp. 1285-1287.

MILD OR BORDERLINE POLYCYTHEMIA (ERYTHROCYTOSIS).

The upper limit of normal hematocrit values is 54 for adult males and 47 for adult females. Patients who smoke or who live above sea level may have elevated hematocrits. The normal hematocrit values for adults, 40-54% for males and 37-47% for females, are determined for patients at sea level; at higher altitudes add 2% for each 4000 ft. (1200 meters). In infants and children the normal hematocrit values are higher than in adults for the first two months of life, lower afterwards and gradually rise until puberty. Wintrobe, M.M.: Clinical Hematology, Ed. 8., p. 1885, Table A-1, A-3; 1891, Table A-15.

DIAGNOSTIC CONSIDERATIONS AND WARNINGS:

LEUKEMOID REACTION (LYMPHOID TYPE).

A high lymphocyte count consisting mostly of mature lymphocytes, thus simulating chronic lymphocytic leukemia (CLL), has been seen in infants and young children with pertussis. A CLL picture has been associated with other diseases including dermatitis herpetiformis, exfoliative dermatitis, chicken pox, cancer of the stomach, metastatic melanoma, breast cancer, and miliary tuberculosis. Wintrobe, M.M.: Clinical Hematology, Ed. 8, p. 1316.

The QBC Physician's Consultant

Hematocrit (%)	= 49.9 normal value for adult males: 40-54%
	normal value for adult females: 37-47%
Platelets ($\times 10^9/L$)	= 525 moderately elevated
Total WBC ($\times 10^9/L$)	= 31.5
Percent Granulocytes (%)	= 65
Granulocytes ($\times 10^9/L$)	= 20.5 markedly elevated
Percent Lymphs+Monos (%)	= 35
Lymphs+Monos ($\times 10^9/L$)	= 11.0 moderately elevated

GENERAL HEMATOLOGIC CLINICAL REMINDERS:

MARKED GRANULOCYTOSIS.
THROMBOCYTOSIS.
LYMPHOCYTOSIS/MONOCYTOSIS.
NORMAL HEMATOCRIT.

SPECIFIC DIAGNOSTIC CONSIDERATIONS INCLUDE:

The pattern of hematologic values obtained is not specific enough to suggest a given diagnosis or syndrome. Further steps to be taken will depend on the patient's history, physical examination, and examination of the blood smear.

The QBC Physician's Consultant

Hematocrit (%)	= 34.0 normal value for adult males: 40-54%
	normal value for adult females: 37-47%
Platelets ($\times 10^9/L$)	= 92 moderately decreased
Total WBC ($\times 10^9/L$)	= 3.2
Percent Granulocytes (%)	= 81
Granulocytes ($\times 10^9/L$)	= 2.6 within normal range
Percent Lymphs+Monos (%)	= 19
Lymphs+Monos ($\times 10^9/L$)	= 0.6 markedly decreased

GENERAL HEMATOLOGIC CLINICAL REMINDERS:

LYMPHOCYTOPENIA.

A decrease in lymphocytes/monocytes occurs in association with bacterial infections, as the result of Cushing's syndrome or corticosteroid administration, in Hodgkin's disease and as the effect of radiation or chemotherapy. It may also be seen in collagen vascular diseases and in acquired immunodeficiency syndrome (AIDS). Additional tests include examination of the peripheral smear and those appropriate to identification of the possible causes of the lymphocytopenia. Wintrobe, M.M.: Clinical Hematology, Ed. 8, p. 1304.

THROMBOCYTOPENIA.

The significance of thrombocytopenia depends on 3 factors: (1) its severity; (2) the rate at which it has developed; and (3) whether or not it is accompanied by changes in red cells and/or leukocytes.

Rapidly developing thrombocytopenia is more likely to be associated with bleeding than gradually increasing thrombocytopenia, other things being equal.

Platelet counts that are reduced below normal (thrombocytopenia) may be due to: (a) increased destruction (immunologic or drug induced), (b) mechanical destruction (splenic dysfunction, portal hypertension and various other causes), (c) increased utilization as in disseminated intravascular coagulation (DIC), (d) massive transfusions, (e) decreased production (chemotherapy, leukemia, and certain drugs), (f) acute infections including viral, bacterial and malarial, (g) certain familial and other disorders. In addition to examination of the peripheral smear, other tests should be carried out as appropriate to clues from the history and physical exam. Wintrobe, M.M.: Clinical Hematology, Ed. 8, pp. 1090-1127 and Table 47-2, p. 1093.

Platelet counts in the 81 to $130 \times 10^9/L$ range are below the normal range but are not associated with a prolongation of bleeding time.

ANEMIA.

Hematocrit values that are below normal signal anemia. Anemia can be due to (a) acute or chronic blood loss, (b) decreased red cell production, caused by infection or inflammation, hypoplasia, neoplasm, or nutritional deficiency, (c) increased red cell destruction/hemolytic anemia. The nature and cause of the anemia should be determined. Suggested additional tests include an examination of the peripheral smear and determination of red blood cell indices as well as a reticulocyte count. Additional tests may include testing the stool for the presence of occult blood and parasites, as well as determination of the total and fractionated serum bilirubin and urinary evidences of hemoglobin breakdown. Wintrobe, M.M.: Clinical Hematology, Ed. 8, pp. 529-558 and Table 20-1, p. 541.

SPECIFIC DIAGNOSTIC CONSIDERATIONS INCLUDE:

The pattern of hematologic values obtained is not specific enough to suggest a given diagnosis or syndrome. Further steps to be taken will depend on the patient's history, physical examination, and examination of the blood smear.

Appendix 2

5

QBC CII SUMMARY
Fri Feb 20 15:39:45 1987

HEMATOCRIT (%) (%, ROUNDED TO " DECIMAL PLACE(S))		
10 ----- CII #	HEMATOCRIT RANGE (after rounding)	DESCRIPTOR
1.	0.0 - 10.0	extremely decreased
15 2.	10.0 - 16.0	extremely decreased
3.	16.0 - 26.0	markedly decreased
4.	26.0 - 34.0	markedly decreased
20 5.	34.0 - 37.0	normal value for adult males: 40-54% normal value for adult females: 37-47%
6.	37.0 - 42.0	normal value for adult males: 40-54% normal value for adult females: 37-47%
25 7.	42.0 - 51.0	normal value for adult males: 40-54% normal value for adult females: 37-47%
8.	51.0 - 55.0	normal value for adult males: 40-54% normal value for adult females: 37-47%
9.	55.0 - 60.0	moderately elevated
30 10.	60.0 - 66.0	markedly elevated
11.	66.0 - 76.0	extremely elevated
12.	76.0 - max	extremely elevated
35		

PLATELETS ($\times 10^9/L$, ROUNDED TO 0 DECIMAL PLACE(S))		
40 ----- CII #	PLATELET RANGE (after rounding)	DESCRIPTOR
1.	0.0 - 19.0	extremely decreased
45 2.	20.0 - 39.0	extremely decreased
3.	40.0 - 79.0	markedly decreased
4.	80.0 - 139.0	moderately decreased
50 5.	140.0 - 440.0	within normal range
6.	441.0 - 700.0	moderately elevated
7.	701.0 - 998.0	markedly elevated
55 8.	999.0 - max	extremely elevated

GRANULOCYTES (x10 ⁹ /L, ROUNDED TO 1 DECIMAL PLACE(S))			

CII #	GRANULOCYTE RANGE (after rounding)	DESCRIPTOR	
5			
1.	0.0 - 0.9	extremely decreased	
2.	1.0 - 1.5	moderately decreased	
10			
3.	1.6 - 1.7	moderately decreased	
4.	1.8 - 3.0	within normal range	
5.	3.1 - 7.2	within normal range	
15			
6.	7.3 - 9.0	moderately elevated	
7.	9.1 - 10.0	moderately elevated	
8.	10.1 - 15.0	moderately elevated	
20			
9.	15.1 - 35.0	markedly elevated	
10.	35.1 - max	markedly elevated	
25			
LYMPHS & MONOS (x10 ⁹ /L, ROUNDED TO 1 DECIMAL PLACE(S))			

CII #	LYMPHS & MONOS RANGE (after rounding)	DESCRIPTOR	
30			
1.	0.0 - 0.5	extremely decreased	
2.	0.6 - 1.0	markedly decreased	
3.	1.1 - 1.6	slightly below normal range	
35			
4.	1.7 - 4.9	within normal range	
5.	5.0 - 6.0	slightly elevated	
6.	6.1 - 12.0	moderately elevated	
40			
7.	12.1 - 20.0	markedly elevated	
8.	20.1 - max	extremely elevated	

Claims

1. An apparatus for the non-interactive, automatic interpretation of hematology results comprising:
 - data processing means which includes,
 - means for evaluating blood-derived parametric values and
 - means for ascertaining a clinically important interval combination applicable to blood-derived parametric values from a listing of plural clinically important intervals and producing output messages therefrom,
 - memory means for storing data and data-processing instructions to be executed by the data processing means,
 - means for entering data which represent the values of hematology parameters derived from a patient's blood and

- means for outputting the messages of hematologic diagnostic significance applicable to the patient, wherein the memory means stores a data base and execution-instructions of an automatically interpreting hematology-diagnostic system which is suitable for operation upon the hematology parameters and their blood-derived values, the data base including:

- 5 - a plurality of messages of hematology diagnostic significance, each message being associated with a range of values for each of the hematology parameters, each range of values constituting one clinically important interval, and
- 10 - a listing of the clinically important intervals within which the blood-derived parametric values may lie, the listing including a series of consecutive clinically important interval numbers and a range of values and a descriptive phrase associated with each clinically important interval,

the stored execution-instructions causing the data processing means to evaluate the blood-derived parametric values and to retrieve from the memory means the one or more messages whose clinically important interval combinations apply to the blood-derived parametric values, wherein the one or more messages are provided in a form to permit the interpretation of the hematologic condition of the patient.

- 15 2. The apparatus according to claim 1 characterized in that said stored execution-instructions further include directions to determine applicable clinically important intervals and associated descriptive phrases, corresponding to each one of the patient's input parametric values, and prepare for output the applicable descriptive phrases.
- 20 3. The apparatus according to claim 2 characterized in that the stored execution-instructions include further directions to the processing means to:
 - 25 - prepare the output for printout with, and aligned to, each applicable descriptive phrase, its associated parameter and the patient-derived value of such associated parameter, and
 - cause a printout, with the prepared descriptive phrase, the thereto aligned prepared items.
- 30 4. The apparatus according to any one of claims 1 to 3 characterized in that the parameters are hematocrit (H), platelet count (P), granulocytes (G) and lymphocyte/monocyte count (L).
- 35 5. The apparatus according to claim 4 characterized in that hematocrit (H) is expressed in percent, and platelet count (P), granulocytes (G), lymphocyte/monocyte count (L), each is expressed in $X 10\%/L$.
- 40 6. The apparatus according to any one of claims 1 to 5 characterized in that the stored data base further includes an individual reminder message number for, and unique to, each reminder message, the message numbers being in a sequence which runs through the hematologic reminder messages and diagnostic reminder messages.
- 45 7. The apparatus according to claim 6 characterized in that the stored data base further includes, for each parameter, and then in turn for each clinically important interval number applicable to that parameter, an array of consecutive one-bit positions, the number of such positions in each array being in correspondence to the reminder message numbers, the arrangement being such that for each reminder message number there appears in the thereto corresponding one bit-positions - all parameters and all their respective clinically important interval number-arrays considered - a binary one in such corresponding bit-positions, for which the parameter and that parameter's clinically important interval number are applicable to the corresponding reminder message number and its reminder message, while elsewhere binary zeroes appear.
- 50 8. The apparatus according to any one of claims 1 to 7 characterized in that said data includes specialized hematological data obtained by quantitative buffy coat analysis of blood in a sample.
- 55 9. The apparatus according to any one of claims 1 to 8 characterized in that said means for outputting messages provides messages in human language.
- 100 10. A method of non-interactively interpreting hematology results, comprising:
 - entering data representing the values of hematology parameters derived from blood into a data processor which includes
 - stored plural messages of hematological diagnostic significance, each message being associated with a range of values for each of a plurality of hematology parameters, and being in a form to permit the interpretation of the hematologic condition applicable to its range, each range of values constituting one clinically important interval, a stored listing of the clinically important intervals within

which the parametric values may lie, the listing including a series of consecutive clinically important interval numbers and a range of values and a descriptive phrase associated with each clinically important interval and stored execution instructions which effect evaluation of parametric values and the retrieval of one or more messages whose clinically important interval combinations apply to the parametric values,

- evaluating the entered data by the stored instructions to retrieve messages applicable to the relevant clinically important intervals and
- producing the applicable messages in sensible form.

Patentansprüche

1. Gerät für die nicht-interaktive, automatische Auswertung hämatologischer Ergebnisse, mit:

- einer Datenverarbeitungseinrichtung, die aufweist:
 - eine Einrichtung zur Auswertung von aus dem Blut hergeleiteten parametrischen Blutwerten und
 - eine Einrichtung zum Bestimmen einer auf die Blutwerte anwendbaren Kombination klinisch bedeutender Intervalle aus einer Auflistung mehrerer klinisch bedeutender Intervalle und zum Erzeugen von Ausgangsmeldungen aus dieser,
- einer Speichereinrichtung zum Speichern von Daten und von der Datenverarbeitungseinrichtung auszuführenden Datenverarbeitungsbefehlen,
- einer Einrichtung zum Eingeben von Daten, welche die Werte der hämatologischen Parameter wiedergeben, die aus dem Blut eines Patienten hergeleitet sind, und
- einer Einrichtung zur Ausgabe der Meldungen von hämatologischer diagnostischer Bedeutung, die auf den Patienten anwendbar sind,

wobei in der Speichereinrichtung eine Datenbank und Ausführungsbefehle eines automatisch auswertenden Hämatologie-Diagnosesystems gespeichert sind, das zum Arbeiten mit den hämatologischen Parametern und deren Blutwerten geeignet ist, wobei die Datenbank aufweist:

- mehrere Meldungen von hämatologischer diagnostischer Bedeutung, wobei jeder Meldung ein Bereich von Werten für jeden der Hämatologieparameter zugeordnet ist und jeder Bereich von Werten ein klinisch bedeutendes Intervall bildet, und
- eine Auflistung der klinisch bedeutenden Intervalle, innerhalb derer die Blutwerte liegen können, wobei die Auflistung eine Folge von aufeinanderfolgenden klinisch bedeutenden Intervallnummern sowie einen Bereich von Werten und eine jedem klinisch bedeutenden Intervall zugehörige beschreibende Phrase enthält,

wobei die gespeicherten Ausführungsbefehle bewirken, daß die Datenverarbeitungseinrichtung die Blutwerte auswertet und in der Speichereinrichtung die eine oder die mehreren Meldungen auffindet, deren klinisch bedeutende Intervalle in Kombination auf die Blutwerte anwendbar sind, wobei die eine oder die mehreren Meldungen in einer Form geliefert werden, die die Auswertung des hämatologischen Zustandes des Patienten gestattet.

2. Gerät nach Anspruch 1, dadurch gekennzeichnet, daß die gespeicherten Ausführungsbefehle ferner Mitteilungen zur Bestimmung anwendbarer klinisch bedeutender Intervalle und der zugehörigen beschreibenden Phrasen enthalten, die jeweils einem der eingegebenen parametrischen Werte des Patienten entsprechen, und die anwendbaren beschreibenden Phrasen für die Ausgabe vorbereiten.

3. Gerät nach Anspruch 2, dadurch gekennzeichnet, daß die gespeicherten Ausführungsbefehle weitere Mitteilungen an die Verarbeitungseinrichtung enthalten, um:

- die Ausgabe zum Ausdrucken vorzubereiten, und zwar mit und korrespondierend zu jeder anwendbaren beschreibenden Phrase, ihrem zugehörigen Parameter und dem vom Patienten hergeleiteten Wert eines solchen zugehörigen Parameters,
- ein Ausdrucken zu bewirken, und zwar mit der vorbereiteten beschreibenden Phrase, den dazu korrespondierenden vorbereiteten Angaben.

4. Gerät nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Parameter Hämatokrit (H), Blutplättchenzahl (P), Granulozytenzahl (G) und Lymphozyten-/Monozytenzahl (L) sind.

5. Gerät nach Anspruch 4, dadurch gekennzeichnet, daß Hämatokrit (H) in Prozent und die Blutplättchenzahl (P), die Granulozytenzahl (G), die Lymphozyten-/Monozytenzahl (L) jeweils in $\times 10^9/L$ ausgedrückt sind.

6. Gerät nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß die gespeicherte Datenbank ferner eine für jede Erinnerungsmitteilung vorgesehene und eindeutige individuelle Erinnerungsmitteilungsnummer enthält, wobei die Mitteilungsnummern in einer Folge vorgesehen sind, welche durch die Hämatologierinnerungsmitteilungen und Diagnostikerinnerungsmitteilungen läuft.
7. Gerät nach Anspruch 6, dadurch gekennzeichnet, daß die gespeicherte Datenbank ferner für jeden Parameter und dann wiederum für jede auf diesen Parameter anwendbare Nummer eines klinisch bedeutenden Intervalls eine Gruppierung aufeinanderfolgender Ein-Bit-Positionen aufweist, wobei die Nummer dieser Positionen in jeder Gruppierung den Nummern der Erinnerungsmitteilungen entspricht und die Anordnung derart ist, daß für jede Erinnerungsmitteilungsnummer in den dieser entsprechenden Ein-Bit-Positionen - unter Berücksichtigung aller Parameter und aller ihrer jeweiligen Gruppierungen der Nummern der klinisch bedeutenden Intervalle - in solchen entsprechenden Bitpositionen eine binäre Eins erscheint, für die der Parameter und die Nummer des klinisch bedeutenden Intervalls dieses Parameters auf die entsprechende Erinnerungsmitteilungsnummer und deren Erinnerungsmitteilung anwendbar sind, während anderweitig binäre Nullen erscheinen.
8. Gerät nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß die Daten spezialisierte hämatologische Daten enthalten, die durch Quantitative-Buffy-Coat-Analyse von Blut in einer Probe gewonnen werden.
9. Gerät nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Einrichtung zur Ausgabe von Mitteilungen die Mitteilungen in menschlicher Sprache liefert.
10. Verfahren zur nicht-interaktiven Auswertung hämatologischer Ergebnisse, mit den Schritten:
 - Eingabe von die Werte von von Blut hergeleiteten Hämatologieparametern repräsentierenden Daten in einen Datenprozessor, welcher aufweist:
 - mehrere gespeicherte Mitteilungen von hämatologischer diagnostischer Bedeutung, wobei jeder Mitteilung ein Bereich von Werten für jeden einer Vielzahl von Hämatologieparametern zugeordnet ist und jede Mitteilung in einer Form vorliegt, die die Auswertung des auf ihren Bereich anwendbaren hämatologischen Zustands gestattet, wobei jeder Wertebereich ein klinisch bedeutendes Intervall bildet, eine gespeicherte Auflistung der klinisch bedeutenden Intervalle, innerhalb derer die parametrischen Werte liegen können, wobei die Auflistung eine Folge aufeinanderfolgender klinisch bedeutender Intervallnummern und einen Bereich von Werten und eine einem klinisch bedeutenden Intervall jeweils zugehörige beschreibende Phrase und Ausführungsbefehle enthält, die die Auswertung der parametrischen Werte und das Auffinden einer oder mehrerer Mitteilungen bewirken, deren klinisch bedeutende Intervalle in Kombination auf die parametrischen Werte anwendbar sind,
 - Auswertung der eingegebenen Daten durch die gespeicherten Befehle zum Auffinden von Mitteilungen, die auf die relevanten klinisch bedeutenden Intervalle anwendbar sind, und
 - Erzeugung der anwendbaren Mitteilungen in verständlicher Form.

Revendications

1. Appareil pour l'interprétation automatique, non-interactive, de résultats hématologiques, comprenant:
 - des moyens de traitement de données qui comportent,
 - des moyens pour évaluer des valeurs de paramètres déduites du sang, et
 - des moyens pour établir une combinaison d'intervalles cliniquement importants, applicable aux valeurs de paramètres déduites du sang, à partir d'une liste de plusieurs intervalles cliniquement importants, et pour produire des messages de sortie à partir de cette combinaison,
 - des moyens de mémoire pour mémoriser des données et des instructions de traitement de données devant être exécutées par les moyens de traitement de données,
 - des moyens pour entrer des données qui représentent les valeurs de paramètres hématologiques déduites du sang d'un patient, et
 - des moyens pour délivrer les messages ayant une signification de diagnostic hématologique qui sont applicables au patient,
 - dans lequel les moyens de mémoire mémorisent une base de données et des instructions d'exécution d'un système de diagnostic hématologique à interprétation automatique, qui est adapté pour agir sur les paramètres hématologiques et leurs valeurs déduites du sang, la base de données

incluant:

- une pluralité de messages ayant une signification de diagnostic hématologique, chaque message étant associé à une plage de valeurs pour chacun des paramètres hématologiques, chaque plage de valeurs constituant un intervalle cliniquement important, et
- une liste des intervalles cliniquement importants à l'intérieur desquels peuvent se trouver les valeurs de paramètres déduites du sang, la liste incluant une série de nombres d'intervalle cliniquement important consécutifs et une plage de valeurs et une phrase descriptive associée à chaque intervalle cliniquement important,

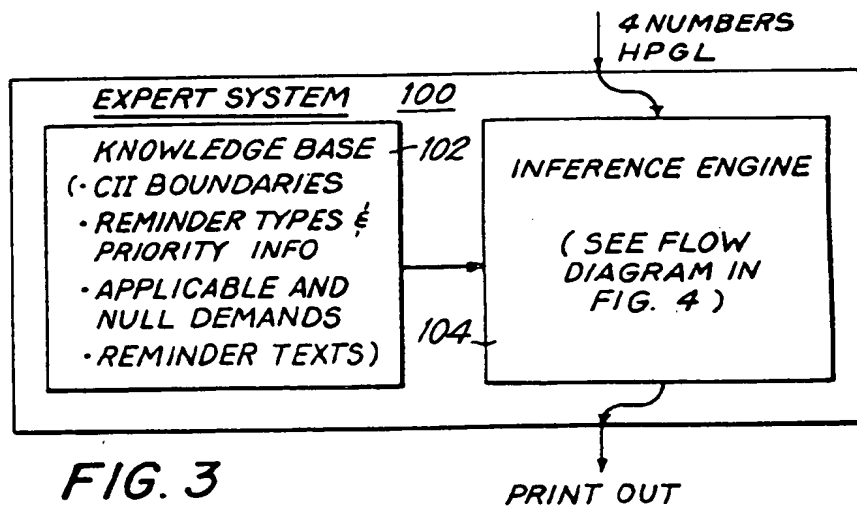
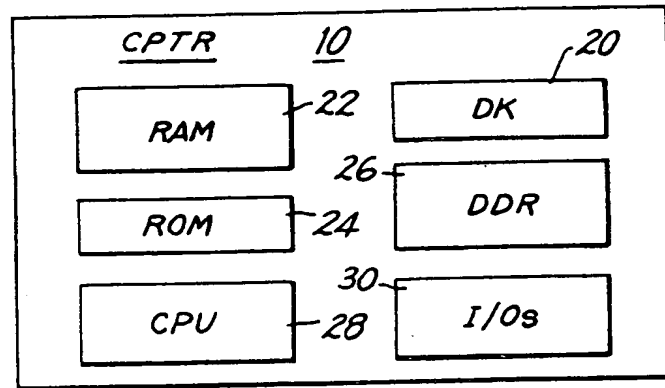
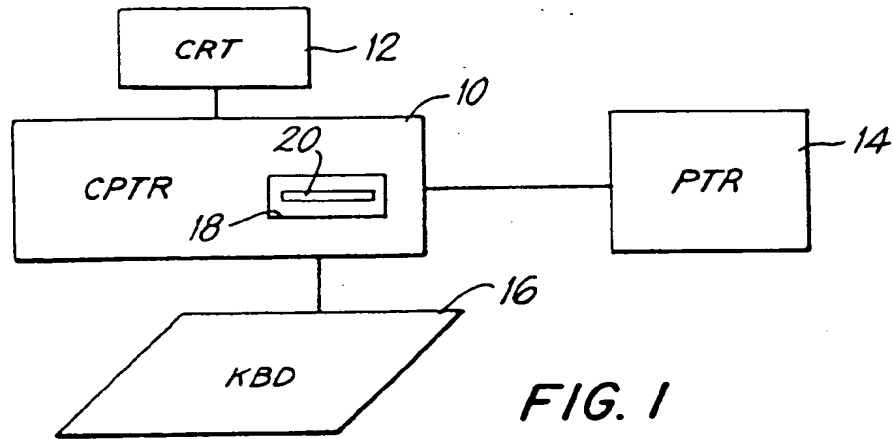
les instructions d'exécution mémorisées amenant les moyens de traitement de données à évaluer les valeurs de paramètres déduites du sang et à extraire des moyens de mémoire le ou les messages dont des combinaisons d'intervalles cliniquement importants s'appliquent aux valeurs de paramètres déduites du sang, le ou les messages étant fournis dans une forme qui permet l'interprétation de l'état hématologique du patient.

2. Appareil selon la revendication 1, caractérisé en ce que lesdites instructions d'exécution mémorisées incluent, en outre, des indications pour déterminer des intervalles cliniquement importants applicables et des phrases descriptives associées, correspondant à chacune des valeurs de paramètres d'entrée du patient, et pour préparer la sortie des phrases descriptives applicables.
3. Appareil selon la revendication 2, caractérisé en ce que les instructions d'exécution mémorisées incluent d'autres indications destinées aux moyens de traitement pour:
 - préparer la sortie sur imprimante, avec chaque phrase descriptive applicable et en alignement avec celle-ci, de son paramètre associé et de la valeur, déduite du patient, de ce paramètre associé, et
 - effectuer une sortie sur imprimante, avec la phrase descriptive préparée, des éléments préparés alignés avec celle-ci.
4. Appareil selon l'une quelconque des revendications 1 à 3, caractérisé en ce que les paramètres sont l'hématocrite (H), le compte des plaquettes (P), les granulocytes (G) et le compte des lymphocytes/monocytes (L).
5. Appareil selon la revendication 4, caractérisé en ce que l'hématocrite (H) est exprimée en pourcent, et le compte des plaquettes (P), les granulocytes (G), le compte des lymphocytes/monocytes (L) sont respectivement exprimés en $\times 10^9/L$.
6. Appareil selon l'une quelconque des revendications 1 à 5, caractérisé en ce que la base de données mémorisée inclut en outre, un nombre de message de rappel individuel destiné à, et spécifique à chaque message de rappel, les nombres de message étant constitués en une séquence qui parcourt les messages hématologiques de rappel et les messages de diagnostic de rappel.
7. Appareil selon la revendication 6, caractérisé en ce que la base de données mémorisée inclut en outre, pour chaque paramètre, puis, à tour de rôle, pour chaque nombre d'intervalle cliniquement important applicable à ce paramètre, un groupement de positions à un bit consécutives, le nombre de ces positions dans chaque groupement étant en correspondance avec les nombres de message de rappel, l'agencement étant tel que, pour chaque nombre de message de rappel, il apparaît dans les positions à un bit correspondant à ce dernier - tous les paramètres et tous leurs groupements de nombres d'intervalle cliniquement important respectifs considérés - un "1" binaire dans ces positions binaires correspondantes, pour lesquelles le paramètre et ce nombre d'intervalle cliniquement important du paramètre sont applicables au nombre de message de rappel correspondant et à son message de rappel, tandis que partout ailleurs apparaissent des "0" binaires.
8. Appareil selon l'une quelconque des revendications 1 à 7, caractérisé en ce que lesdites données incluent des données hématologiques spécialisées, obtenues par analyse quantitative du caillot blanc du sang dans un échantillon.
9. Appareil selon l'une quelconque des revendications 1 à 8, caractérisé en ce que lesdits moyens pour délivrer des messages fournissent des messages dans un langage humain.
10. Procédé pour interpréter, de manière non-interactive, des résultats hématologiques, comprenant:
 - l'entrée de données représentant les valeurs de paramètres hématologiques déduites du sang dans

un processeur de données qui inclut

plusieurs messages mémorisés ayant une signification de diagnostic hématologique, chaque message étant associé à une plage de valeurs pour chaque paramètre d'une pluralité de paramètres hématologiques, et étant dans une forme qui permet l'interprétation de l'état hématologique applicable à sa plage, chaque plage de valeurs constituant un intervalle cliniquement important, une liste mémorisée des intervalles cliniquement importants à l'intérieur de laquelle peuvent se trouver les valeurs de paramètres, la liste incluant une série de nombres d'intervalle cliniquement important consécutifs et une plage de valeurs et une phrase descriptive associée à chaque intervalle cliniquement important et des instructions d'exécution mémorisées qui effectuent une évaluation de valeurs de paramètres et l'extraction d'un ou de plusieurs messages dont des combinaisons d'intervalles cliniquement importants s'appliquent aux valeurs de paramètres,

- l'évaluation des données entrées, par les instructions mémorisées, pour extraire des messages applicables aux intervalles cliniquement importants concernés, et
- la production des messages applicables, dans une forme perceptible.



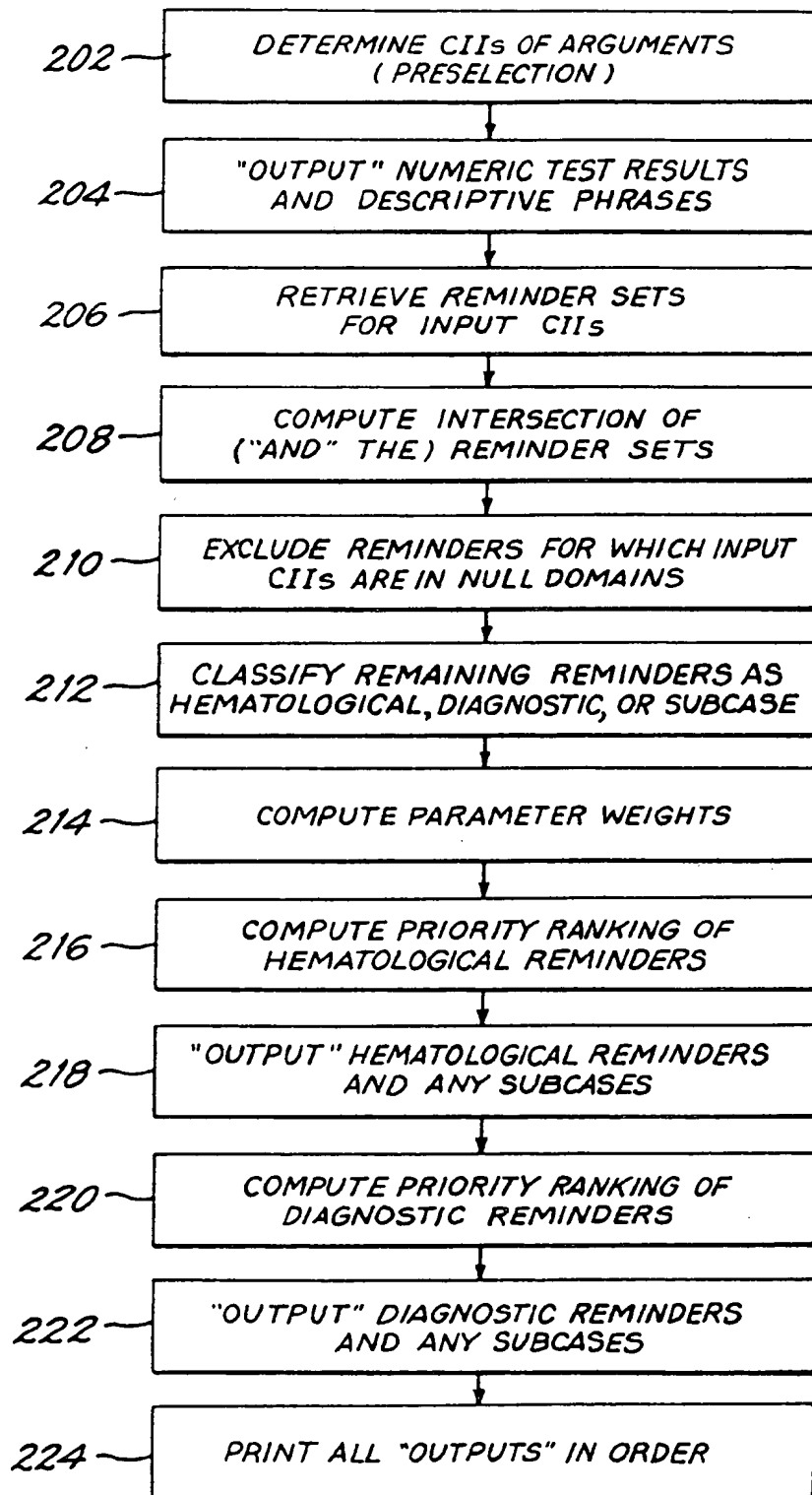


FIG. 4